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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,728	08/03/2001	Robert James Tribe	0100/0131	5066
21395 LOUIS WOO	7590 07/24/200	3	EXAMINER	
	OF LOUIS WOO		DESANTO, MATTHEW F	
717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			3763	
			MAIL DATE	DELIVERY MODE
			07/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)				
Office Action Summary		09/920,728	TRIBE ET AL.				
		Examiner	Art Unit				
		MATTHEW F. DESANTO	3763				
Period fo	The MAILING DATE of this communication apported in the plant of the plant is a second or the	pears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)[\	Responsive to communication(s) filed on 26 J	une 2007					
•	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.						
<i>'</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
٥,١	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
		annlication					
•	Claim(s) <u>1,4,5 and 7-12</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.						
′=	5) Claim(s) is/are allowed. 6) Claim(s) <u>1,4,5 and 7-12</u> is/are rejected.						
·	Claim(s) is/are objected to.						
•	Claim(s) are subject to restriction and/o	or election requirement					
		r election requirement.					
Applicati	on Papers						
-	The specification is objected to by the Examine						
10)	10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	9 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
2)  Notic 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate				

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. The examiner is unclear as to whether the claims 11 and 12 are trying to claim an algorithm that compares the pressure sensed to the stored pressure as a functional language step as opposed to a structural limitation. Therefore, the examiner is unclear as to how to interpret the functional steps of the force sensor since the steps seem to recite the intended use of the sensor and the control unit, which caused the examiner to be confused and need further clarification.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 5. Claims 1, 5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Ford (USPN 6,551,277).

Ford discloses a syringe pump having a drive mechanism 7, an occlusion detector including a force sensor that directly senses the force exerted on the plunger in response to an occlusion. Ford's pump is operable in response to a detected occlusion to reverse the drive applied to move the plunger along the barrel sufficiently until the force detected by the force sensor falls by a predetermined amount (columns 1-5).

# Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 4 and 8, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford.

Ford discloses the invention substantially as claimed. Ford discloses that upon occlusion detection by the sensor, the pump rewinds by some predetermined amount following an occlusion alarm (incremental drive system rewind) [Column 5]. However, Moberg fails to specifically disclose the pump being arranged to reverse the drive until force detected by the force sensor is substantially 10% of the force at which an occlusion is detected, and the force applied to drive the plunger is changed to reduce the detected force to substantially 10% of the predetermined value. This predetermined

value is deemed matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ford in view of Moberg (US 6,362,591).

Ford discloses the invention substantially as claimed except for the pump generating an alarm when force of the plunger exceeds a predetermined value when there is an occlusion.

Moberg teaches that it is known to have an alarm in syringe pumps when force of the plunger exceeds a predetermined value when there is an occlusion. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ford' syringe pump by including an alarm in its syringe pump for indicating occlusions due to exceeding predetermined values, since Moberg suggests that such modification would provide an audible indication to the user for occlusions.

### Response to Arguments

- 9. Applicant's arguments filed 6/26/07 have been fully considered but they are not persuasive.
- 10. The examiner has read through applicant's argument and is not convinced because Ford has a sensor that determines the force that is exerted on the plunger and the retainer mechanism which is directly linked to any force that is exerted on the plunger head, since the plunger head is attached to the plunger which is in connection

with the retainer mechanism. Therefore any increase in pressure on the plunger head translate into increased pressure on the plunger and the retainer mechanism.

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11. Ford has a control unit that controls the movement of the plunger and retainer mechanism to reverse direction once the pressure increases (Column 5, lines 39-45), therefore inherently teaching a force max if the control unit is comparing the pressure to a set level, since it needs to increase in order to trigger the motor to go in reverse (Column 5, lines 39-45) and this can occur when the device is expelling fluid and an occlusion occurs that increases pressure in the infusion line (Column 5, lines 52-59), thus causing the plunger to be retraced (since that is how the device works).

#### Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto Art Unit 3763

/Matthew F DeSanto/ Primary Examiner, Art Unit 3763